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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,982	03/30/2004	Valery M. Dubin	043395-0377973	8631

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Pillsbury Winthrop Shaw Pittman LLP  
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EXAMINER
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JUNG, UNSU

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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11/27/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket\_ip@pillsburylaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,982	<b>Applicant(s)</b> DUBIN ET AL.	
	<b>Examiner</b> UNSU JUNG	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-16, 19-21 and 54-59 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-16, 19-21 and 54-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on July 20, 2009 has been entered. The submission included amendments to claims 1, 14, and 57.

### ***Status of Claims***

2. Claims 1-5, 7-16, 19-21, and 54-59 are pending, claim 5 has been previously withdrawn from consideration, and claims 1-4, 7-16, 19-21, and 54-59 are currently under consideration for patentability under 37 CFR 1.104.

### ***Priority***

3. The instant application has a filing date of March 30, 2004 and does not claim for the benefit of a prior-filed application.

***Rejections Withdrawn***

4. The rejection of claims 1-4, 7-16, 19-21, 54, and 55 under 35 U.S.C. 112, second paragraph has been withdrawn in view of amended claims 1 and 14 in the reply filed on July 20, 2009.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**8. The following prior art rejections may include modified portions, which have been bolded, due to amended claims 1 and 14 in the reply filed on July 20, 2009.**

9. Claims 1-4, 7-12, 19-21, 54, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio et al. (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003) (hereinafter "DeNuzzio"), Chazalviel et al. (*Applied Spectroscopy*, 1993, Vol. 47, pp1411-1416) (hereinafter "Chazalviel"), and Yoshida et al. (JP 07-184883 A, July 25, 1995) (hereinafter "Yoshida").

Li teaches an apparatus comprising a condensed array addressed device (see entire document, particularly p8) including a plurality of addressable cells (p8, Detailed Description of the Invention, 1st paragraph), each of the plurality of addressable cells including at least two electrodes (reference elements 1 and 5 in Fig. 2; reference elements 1 and 3 in Fig.'s 1 and 3; and reference elements 3 and 4 in Fig. 5); and a spectroscope optically coupled to the condensed array addressed device (p34, last paragraph and p35). The apparatus of Li further includes microfluidic trench for

Art Unit: 1641

containing one or more target molecules (reference element 7 in Fig.'s 1 and 3 and p39, 1<sup>st</sup> paragraph) **and a self-assembled monolayer (p17, 1<sup>st</sup> full paragraph and p23, last paragraph), which reads on the claimed limitation of “a self-assembled interlayer configured to modulate a coverage on the electrodes.”**

With respect to the limitation of "electrodes having structures and/or charge distributions similar to the target molecule" as recited in claim 1, Li teaches that electrodes further comprises probe molecules that specifically bind to interact with target molecules (p4, last paragraph-p5, 1<sup>st</sup> paragraph) and that the probe molecules can include nucleotide sequence, which hybridizes with a target DNA (molecular recognition, p12, 2<sup>nd</sup> paragraph).

With respect to claims 8 and 9, Li teaches that the plurality of addressable cells includes an individually addressable cell, which includes a first individually addressable electrode and a second individually addressable electrode (p8, Detailed Description of the Invention, 1<sup>st</sup> paragraph).

With respect to claims 10-12, Li teaches that spacing between the electrodes is less than 1  $\mu\text{m}$  (p17, 5th paragraph). Li further teaches that cross-dimensions of microchannels, in which the electrodes are located, are in the order of 0.1 to 500  $\mu\text{m}$  (p19, 1<sup>st</sup> paragraph and Fig. 9C). Therefore, one of ordinary skill in the art would recognize that the electrodes located within the microchannels would have less than 100 nm in size since the electrodes contained within the microchannels would necessarily have to be less than the cross-dimensions of microchannels.

With respect to claim 19, Li teaches an apparatus, further comprising a microfluidic channel coupled to at least one of the addressable cells (p18, last paragraph and p19, 1st paragraph).

With respect to claims 20 and 21, Li teaches an apparatus, further comprising selective membranes (porous polymeric pads), which includes chemically and biologically selective membranes (p5, last paragraph).

With respect to claim 54, Li teaches a target molecule comprising DNA (p12, 2<sup>nd</sup> paragraph).

With respect to claim 56, Li teaches that the electrodes are solid state electrodes (p3, Summary of the Invention, 3<sup>rd</sup> paragraph).

Li further teaches that a variety of detection methods can be used with the condensed array addressed device including optical detection methods capable of detecting spectral changes upon changes in redox state including fluorescence, phosphorescence, luminescence, chemiluminescence, electrochemiluminescence, and refractive index detection methods. However, Li does not specifically teach that two different detection means, electrochemical and optical (spectroscope), are coupled to the array device. Li further does not specifically teach an apparatus further comprising a waveguide, which includes a total internal reflection prism, wherein the spectroscope is optically coupled to the total internal reflection prism.

DeNuzzio teaches microfabricated sensors with multiple working electrodes coupled to both optical and electrochemical detection means allowing the combination of the multiplexed electrochemical detection with optical detection in a single planar

Art Unit: 1641

microcell (see entire document, particularly Abstract and p5, paragraph [0014]). The combination of various electrochemical, photometric, and other measurement results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously (p9, paragraph 0030]).

With respect to claims 1-3, Chazalviel teaches Fourier Transform (FT)-infrared (IR) spectroscopy, which is a well-known spectral detection method at the electrochemical interfaces (entire document, particularly p1416, *Conclusion*). The advantages of FT-IR spectroscopy are well known (p1416, *Conclusion*). The advantages include good sensitivity and ability to smoothly extract varying contributions due to electronic absorptions and to obtain spectra as complex quantities, which is of considerable help in the identification of the vibration signals and in their ascription to one or the other of the many possible electrochemical processes (p 1416, *Conclusion*).

With respect to claims 1 and 7, Yoshida teaches an optical system comprising FT-IR spectroscopy and an ATR (attenuated total internal reflection) prism, which provides infrared rays to infrared analysis equipment such as FT-IR spectroscopy (see entire translated document, particularly Abstract and paragraph [0005]).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ combination of both optical and electrochemical detectors of Li as taught by DeNuzzio in order to allow a combination of multiplexed electrochemical detection with optical detection in a single device.

The advantage of allowing a combination of multiplexed electrochemical detection with optical detection in a single device provides the motivation to combine



Art Unit: 1641

teachings of Li and DeNuzzio since the combination of various electrochemical, photometric, and other measurement results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously.

Further, one of ordinary skill in the art would have had a reasonable expectation of success in employing the combination of both optical and electrochemical detectors in the device of Li since DeNuzzio teaches that simultaneous detection of both optical and electrochemical signals is possible with the combination of the multiplexed electrochemical detection with optical detection.

Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the FT-IR spectroscopy of Chazalviel in the apparatus of Li in view of DeNuzzio in order to provide a spectral detection device at the electrochemical interfaces of the condensed array addressed device of Li in view of DeNuzzio for optical detection of biomolecular interactions.

The advantage of employing a sensitive detection device, which facilitates spectra information in complex quantities, provides the motivation to employ the FT-IR spectroscopy of Chazalviel in the apparatus of Li in view of DeNuzzio with a reasonable expectation of success since the FT-IR spectroscopy is capable of smoothly extracting varying contributions due to electronic absorptions and obtaining spectra in complex quantities permitting identification of the vibration signals.

In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select FT-IR spectroscopy as a detection system,

Art Unit: 1641

since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. Because the claimed apparatus is known in the prior art and has been disclosed as being used with a spectroscope in general, the selection of a specific type of a spectroscope in itself does not present a novel feature of the claimed invention. Since one of ordinary skill in the art at the time of the invention would recognize that a plurality of different types of detection system can be used in the apparatus of Li in view of DeNuzzio for detection of biomolecular interactions based on the same principle of detecting electrochemical species, it would have been obvious to employ a FT-IR spectroscopy as a detection system in the instant claims.

Moreover, it would have been *prima facie* obvious to further include a total internal reflection prism (waveguide), which is optically coupled to the FT-IR spectroscope as taught by Yoshida in the apparatus of Li in view of DeNuzzio and Chazalviel as it is generally known to use total internal reflection prisms in order to provide infrared rays to FT-IR spectroscope. Since the FT-IR spectroscopy of Yoshida can be coupled to the electrochemical interfaces of the condensed array addressed device of Li as set forth above and the electrochemical interfaces of Li DeNuzzio and Chazalviel includes a microfluidic trench containing addressable cells having at least two electrodes, the combined teachings of Li, DeNuzzio, Chazalviel, and Yoshida meet the amended feature of “the waveguide total internal reflection prism is coupled to the microfluidic trench.”

With respect to claim 4, the limitation of "the infrared spectroscope is electromodulated by applying potential between the at least two electrodes in at least one of the plurality of cells" is a recitation of the intended use of the claimed invention and must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The apparatus of Li in view of DeNuzzio, Chazalviel, and Yoshida meets all the structural limitation of claim 4 and would therefore be capable of performing the intended use limitation above. Further, Li teaches that a potential is applied between the two electrodes in the plurality of cells (p34, 4m paragraph).

**With respect to claim 57, the recitation that the apparatus can sense a change in a rate of electrolysis is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138 (CCPA 1946); *In re Swinehart*, 169 USPQ 226 (CCPA 1971); and *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). A patent applicant is free to recite features of an apparatus either structurally or functionally. See *In re Swinehart*, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) (" [T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. As our predecessor court stated in *In re Swinehart*, 439 F.2d at 213, 169 USPQ at 228:**

**where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter**

**may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on**

**Therefore, the feature of “the apparatus can sense a change in a rate of electrolysis” would be an inherent/intrinsic characteristic of the apparatus of Li in view of DeNuzzio, Chazalviel, and Yoshida since the apparatus of Li in view of DeNuzzio, Chazalviel, and Yoshida meets all the structural limitations of the claimed invention.**

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003), Chazalviel (Applied Spectroscopy, 1993, Vol. 47, pp1411-1416), and Yoshida (JP 07-184883 A, July 25, 1995) as applied to claims 1 and 10 above, and further in view of Dai et al. (U.S. Patent No. 6,528,020, Mar. 4, 2003) (hereinafter “Dai”).

Li in view of DeNuzzio, Chazalviel, and Yoshida teaches an apparatus comprising a condensed-array addressed device and an optically coupled spectroscope as set forth above. Li further teaches that each of the pair of electrodes includes carbon nanotubes (p23, 3<sup>rd</sup> paragraph). However, Li in view of DeNuzzio, Chazalviel, and Yoshida does not specifically teach that each of the pair of electrodes includes single-walled carbon nanotubes or silicon nanowires.

Dai teaches chemical/biological sensors comprising electrochemical nanotube devices, which demonstrate significant and robust response and more significantly tunable selectivity to chemical or biological species in their environments (see entire document). The nanotube is generally single-walled carbon nanotube or silicon nanotubes (nanowires, column 2, lines 21-27 and column 4, lines 17-22).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to specifically employ single-walled carbon nanotubes or silicon nanowires of Dai as the nanotubes associated with the pair of electrodes of Li in view of DeNuzzio, Chazalviel, and Yoshida, as it is well known that the electrochemical nanotube devices demonstrate significant and robust response and more significantly tunable selectivity to chemical or biological species in their environments.

In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select single-walled carbon nanotubes or silicon nanowires as a layer covering the electrodes of the condensed array addressed device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. Because the claimed apparatus is known in the prior art and has been disclosed as being capable of being used with carbon nanotubes in general, the selection of a specific type of a nanotube/nanowire in itself does not present a novel feature of the claimed invention. Since one of ordinary skill in the art at the time of the invention would recognize that a plurality of different types of nanotubes/nanowires can be used in the apparatus of Li in view of DeNuzzio,

Chazalviel, and Yoshida for detection of biomolecular interactions based on the same principle of detecting electrochemical species, it would have been obvious to employ a single-walled carbon nanotubes or silicon nanowires in the instant claims.

11. Claims 14-16, 55, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003), Ito (U.S. Patent No. 5,384,028, Jan. 24, 1995), and Girault et al. (U.S. Patent No. 5,512,489, Apr. 30, 1996) (hereinafter "Girault").

Li teaches an apparatus comprising a condensed array addressed device (see entire document, particularly p8) including a plurality of addressable cells (p8, Detailed Description of the Invention, 1st paragraph), each of the plurality of addressable cells including at least two electrodes (reference elements 1 and 5 in Fig. 2; reference elements 1 and 3 in Fig.'s 1 and 3; and reference elements 3 and 4 in Fig. 5); and a spectroscope optically coupled to the condensed array addressed device (p34, last paragraph and p35). The apparatus of Li further includes microfluidic trench for containing one or more target molecules (reference element 7 in Fig.'s 1 and 3 and p39, 1<sup>st</sup> paragraph) **and a self-assembled monolayer (p17, 1<sup>st</sup> full paragraph and p23, last paragraph), which reads on the claimed limitation of "a self-assembled interlayer configured to modulate a coverage on the electrodes."**

With respect to claim 14, Li teaches that the plurality of addressable cells define a plurality of sensor elements configured as an array, wherein each of the sensor

Art Unit: 1641

elements is functionalized to interact with one or more target molecules (p23, 2<sup>nd</sup> -7<sup>th</sup> paragraphs); and further comprising control circuitry coupled to the sensor elements, wherein the control circuitry is configured to detect interactions of the sensors with the target molecules (p24, 4th paragraph). The addressable cells of Li contain a first electrode and a second electrode (reference elements 1 and 3 in Fig.'s 1 and 3; and reference elements 3 and 4 in Fig. 5), wherein the first tip of the first electrode and the second tip of the second electrode are located in the microfluidic trench (Fig.'s 1 and 3). The first electrode and the second electrode are each coupled to first and second traces (input and outputs) via first and second conductive plugs, respectively (Fig. 5 and p17, 2<sup>nd</sup> paragraph). With respect to the limitation of "electrodes having structures and/or charge distributions similar to the target molecule" as recited in claim 14, Li teaches that electrodes further comprises probe molecules that specifically bind to interact with target molecules (p4, last paragraph-p5, 1<sup>st</sup> paragraph) and that the probe molecules can include nucleotide sequence, which hybridizes with a target DNA (molecular recognition, p12, 2<sup>nd</sup> paragraph).

With respect to claims 15 and 16, Li teaches the plurality of sensor elements configured as a two-dimensional high-density array (p39, 3<sup>rd</sup> paragraph), which are addressable by corresponding rows and columns.

With respect to claim 55, Li teaches a target molecule comprising DNA (p12, 2<sup>nd</sup> paragraph).

With respect to claim 58, Li teaches a signal amplifier (p37, 3<sup>rd</sup> paragraph).

Li further teaches that a variety of detection methods can be used with the condensed array addressed device including optical detection methods capable of detecting spectral changes upon changes in redox state including fluorescence, phosphorescence, luminescence, chemiluminescence, electrochemiluminescence, and refractive index detection methods. However, Li does not specifically teach that two different detection means, electrochemical and optical (spectroscope) detectors are coupled to the array device. Li further teaches that other electronic components can be added to the apparatus including circuitry that allows signal processing (p24, 4th paragraph). However, Li is silent on an apparatus further comprising memory coupled to the control plurality of sensor elements in the memory. The apparatus of Li includes an array addressed device in a microarray format as set forth above. Although the microarray format of Li would allow the apparatus of Li to be hand-held, Li fails to explicitly teach that the apparatus is a hand-held device.

DeNuzzio teaches microfabricated sensors with multiple working electrodes coupled to both optical and electrochemical detection means allowing the combination of the multiplexed electrochemical detection with optical detection in a single planar microcell (see entire document, particularly Abstract and p5, paragraph [0014]). The combination of various electrochemical, photometric, and other measurements results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously (p9, paragraph 0030)).

Ito teaches that a memory device for storing data can be provided with a biosensor for storing data (see entire document, particularly Abstract). The data include



Art Unit: 1641

a fabrication date for the biosensor, a lot number, an effective period of the biosensor, biosensor characteristics, measured date, measuring time, and measured results (Abstract).

Girault teaches a device which need not be laboratory bound (see entire document, particularly column 3, lines 52-57). The device is a multi-heavy metal ion detector directed essentially at in-the-field measurement which may be used as a portable hand-held device or form part of a remote sensing network (column 3, lines 52-57). The device of Girault et al. electroanalysis can be easily adapted to enzyme chemistry or/and immunochemistry for use as a biosensor (column 7, lines 12-20).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ a combination of both optical and electrochemical detectors of Li as taught by DeNuzzio in order to allow a combination of multiplexed electrochemical detection with optical detection in a single device.

The advantage of allowing a combination of multiplexed electrochemical detection with optical detection in a single device provides the motivation to combine teachings of Li and DeNuzzio since the combination of various electrochemical, photometric, and other measurement results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously.

Further, one of ordinary skill in the art would have had a reasonable expectation of success in employing the combination of both optical and electrochemical detectors in the device of Li since DeNuzzio teaches that simultaneous detection of both optical

and electrochemical signals is possible with the combination of the multiplexed electrochemical detection with optical detection.

In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include the memory device of Ito, which is configured to store data, coupled to the control circuit of Li in view of DeNuzzio in order to store data associated with plurality of sensor elements.

The advantage of storing data, which may include a fabrication date for the biosensor, a lot number, an effective period of the biosensor, the biosensor characteristics, measured date, the measuring time, and the measured results, provides the motivation to include the memory device of Ito coupled to the control circuit of Li in view of DeNuzzio with a reasonable expectation of success.

Although Li in view of DeNuzzio and Ito fails to explicitly teach that the apparatus is a hand-held device, one of ordinary skill in the art at the time of the invention would have been motivated to construct the apparatus of Li in view of DeNuzzio and Ito in a hand-held device format with a reasonable expectation of success since Girault teaches that electrode array biosensor devices can be used as a portable hand-held device, which need not be laboratory bound and has the advantage of allowing in-the-field measurements.

12. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003), Ito (U.S. Patent No. 5,384,028, Jan.

Art Unit: 1641

24, 1995), and Girault (U.S. Patent No. 5,512,489, Apr. 30, 1996) as applied to claim 14 above, and further in view of Torch (U.S. Patent No. 6,163,281, Dec. 19, 2000) and Wohlstadter et al. (U.S. Patent No. 6,090,545, July 18, 2000) (hereinafter "Wohlstadter").

Li in view of DeNuzzio, Ito, and Girault teaches an apparatus comprising a condensed-array addressed device and an optically coupled spectroscope as set forth above. However, Li in view of DeNuzzio, Ito, and Girault fails to teach an apparatus further comprising a video display.

Torch teaches that data may be displayed graphically on a computer of video screen or other electronic display device (see entire document, particularly column 8, lines 13-29).

Wohlstadter teaches that signal processing means such as a digital computer can be used for transferring, recording, analyzing and/or displaying the results of assays (see entire document, particularly column 42, lines 59-63).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ a computer of Torch with a video screen/display in the apparatus of Li in view of DeNuzzio, Ito, and Girault in order to use the computer for transferring, recording, analyzing and/or displaying the results of assays. The advantage of allowing the transfer, recording, analysis and/or displaying of the assay results provides the motivation to combine teachings of Li in view of DeNuzzio, Ito, and Girault and Torch with a reasonable expectation of success since

Wohlstadter teaches that signal processing means such as a digital computer can be used for transferring, recording, analyzing and/or displaying the results of assays.

### ***Response to Arguments***

13. Rejection of claims 1-4, 7-12, 19-21, 54, 56, and 57 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio, Chazalviel, and Yoshida

Applicant's arguments filed on July 20, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed herein.

Applicant's argument that none of the prior art references teaches "a self-assembled interlayer configured to modulate a coverage on at least one of the first or second electrodes" has been fully considered but is not found persuasive in view of the rejections in this Office Action. As stated above, Li does teach a self-assembled monolayer (p17, 1<sup>st</sup> full paragraph and p23, last paragraph), which reads on the claimed limitation of "a self-assembled interlayer configured to modulate a coverage on the electrodes."

In view of the foregoing response to arguments, the rejection of claims 1-4, 7-12, 19-21, 54, 56, and 57 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio, Chazalviel, and Yoshida has been maintained.

14. Rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over DeNuzzio, Chazalviel, and Yoshida, and further in view of Dai

Applicant's arguments filed on July 20, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed above.

In view of the foregoing response to arguments, the rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio, Chazalviel, and Yoshida, and further in view of Dai has been maintained.

15. Rejection of claim 14-16, 55, and 58 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio, Ito, and Girault

Applicant's arguments filed on July 20, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed herein.

Applicant's argument that none of the prior art references teaches "a self-assembled interlayer configured to modulate a coverage on at least one of the first or second electrodes" has been fully considered but is not found persuasive in view of the rejections in this Office Action. As stated above, Li does teach a self-assembled monolayer (p17, 1<sup>st</sup> full paragraph and p23, last paragraph), which reads on the claimed limitation of "a self-assembled interlayer configured to modulate a coverage on the electrodes."

In view of the foregoing response to arguments, the rejection of claims 14-16, 55, and 58 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio, Chazalviel, Ito, and Girault has been maintained.

Art Unit: 1641

16. Rejection of claim 59 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio, Ito, and Girault, and further in view of Torch and Wohlstadter

Applicant's arguments filed on July 20, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed above.

In view of the foregoing response to arguments, the rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Li in view of DeNuzzio, Ito, and Girault, and further in view of Torch and Wohlstadter has been maintained.

17. Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

***Conclusion***

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

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/Unsu Jung/  
Unsu Jung  
Primary Examiner  
Art Unit 1641